



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/737,633	11/15/1996	FABRIZIO SAMARITANI	P/42-60	5401

7590 05/14/2004

Edward A Meilman  
Dickstein Shaprio Morin & Oshinsky LLP  
1177 Avenue of the Americas  
41st Floor  
New York, NY 10036-2714

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/737,633

**Applicant(s)**

SAMARITANI ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6-13 and 15 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/04 has been entered.

***1. Formal Matters***

- A. The Amendment dated 2/4/04, has been entered into the record.
- B. Claims 1-15 are pending in this Office Action. Claims 2 and 5 have been canceled. Therefore, claims 1, 3, 4, and 6-15 are the subject of this Office Action.

***2. Claim Rejections - 35 USC § 103***

- A. All rejections under 35 USC 103 have been withdrawn in view of Applicants' arguments and the Declaration provided by Mark Manning. Applicants' major persuasive arguments are as follows: (1) Hanisch indicate that a low pH solution does not require a stabilizer. Though a stabilizer may not be required, there is no evidence that the use of a stabilizer would be problematic. However, in view of the remaining arguments, this issue has not been further raised by the Examiner. In addition to the fact that Hanisch do not teach a stabilized liquid formulation, the other major points raised by Applicants are (2) that Hanisch teach that for low pH formulations of IFN, PPF is preferred to albumin. (3) given the large changes in the pH during the processing described by Hanisch, the choice of a single buffer would be problematic. (4) Hershenson, the secondary reference, does not teach the use of acetate buffers or mannitol, but do teach that glycerol or PEG are used in every buffer composition described, unlike the present invention. Similarly, Cymbalista, who teach the use of acetate buffers, do not teach that PVP can be eliminated from theses buffered solutions. These reasons, coupled with the unexpected results of half-life of the claimed composition, led the Examiner to withdrawn the rejection under 35 USC 103.

Art Unit: 1647

### **3. Claim Objections**

A. Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 14 is a substantial duplicate (in fact, identical) to claim 10.

The Examiner apologizes for mailing an Office Action simply for a claim objection, but, due to the complex prosecution history and time constraints, an Office Action needed to be mailed.

### **Advisory information**

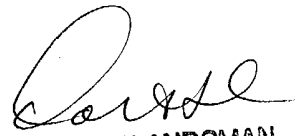
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
May 14, 2004



**ROBERT LANDSMAN**  
**PATENT EXAMINER**